Environmental Management Consolidated Business Center
Ash Fall Project

Quality Assurance Project Plan

Revision: 0
Effective Date is 3 days after the date of approval

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A. Introduction

This Ash Fall Project Quality Assurance Project Plan (QAPP) describes the requirements and process that the Office of Environmental Management, Consolidated Business Center (EMCBC) utilizes in conducting its Quality Assurance (QA) program for the Ash Fall Project in support of the Environmental Management Office of River Protection (ORP) mission for Environmental Management (EM). This QAPP is based on EM-QA-001, EM *Quality Assurance Program* (QAP) and NQA-1, 2008/2009a, *Quality Assurance Requirements for Nuclear Facility Applications*.

B. Quality Assurance Policy

The EMCBC Office of Technical Support and Asset Management shall conduct oversight in compliance with this QAPP. It is the mandatory responsibility of affected Ash Fall Project personnel to comply with this QAPP and the supporting Ash Fall Project documents.

C. Ash Fall Project QAPP

This QAPP describes the organizational structure, the interfaces, and the general QA program requirements applicable to the Ash Fall Project. The *EMCBC QAPP Implementation Requirements Matrix*, AFP-MTX-1.0 (Attachment A), provides the road map for each applicable QAPP Section to the specific Ash Fall Project procedure(s) implementing the requirements of EM-QA-001 and NQA-1, 2008/2009a.

D. Work Planning and Oversight

The ORP Engineering Lead provides the overall direction for this project. The EMCBC Assistant Director, Office of Technical Support and Asset Management provides input to ORP Engineering Lead regarding the Ash Fall Project budget and work scope. The EMCBC Assistant Director, Office of Technical Support and Asset Management shall appoint a QA Lead for the Ash Fall Project. The QA Lead ensures the implementation of the approved work scope in accordance with the QAPP and Ash Fall Project implementing procedures.

Based on input from the ORP Engineering Lead and the EMCBC Assistant Director, the QA Lead shall ensure that adequate oversight of the Ash Fall Project related activities are conducted appropriately and assessed on a scheduled basis, including the Management Assessment of the Ash Fall Project process.

E. Scheduled Frequency Tolerance

Oversight activities addressed by this QAPP and implementing documents that specify a scheduled frequency for the performance of an oversight activity may be extended by 25% at the discretion of the QA Lead. The justification for each individual use of this flexibility shall be documented.

1.0 ORGANIZATION

The ORP Engineering Lead is the overall Project Manager for the Ash Fall Project. In support of the ORP Engineering Lead, the EMCBC Assistant Director, Office of Technical Support and Asset Management shall establish an organizational structure to manage and accomplish the QAPP activities. In addition, EMCBC Assistant Director, Office of Technical Support and Asset Management interfaces with the ORP Engineering Lead for support in maintaining procedures, documents, records, personnel training, qualification, and any required certifications, if applicable.

1.1 Ash Fall Project Staff

The following individuals responsible for establishing and executing the QAPP may delegate any or all of the work to others but shall retain responsibility for the delegated work:

- ORP Engineering Lead
- EMCBC Assistant Director, Office of Technical Support and Asset Management
- EMCBC Coordinator
- EMCBC Assistant Director, Office of Information Resource Management
- EMCBC Information Technology (IT) Coordinator
- QA Lead
- Desert Research Institute (DRI) Staff
- United States Geological Survey (USGS) Staff
- National Oceanic and Atmospheric Administration (NOAA) Staff

Such delegation shall be documented by memorandum and the memorandum shall be included in the record file for the activity that was conducted under the delegation.

1.2 ORP Engineering Lead

The ORP Engineering Lead, including support staff, is responsible for the overall Ash Fall Project execution, coordination of the QA and technical activities, and is also responsible for the conduct of a Management Assessment during the life of the

Ash Fall Project. The ORP Engineering Lead also provides overall program management direction and funding in coordination with the EMCBC Assistant Director, Office of Technical Support and Asset Management.

1.3 EMCBC Assistant Director, Office of Technical Support and Asset Management

The EMCBC Office of Technical Support and Asset Management has responsibility for coordinating the development, implementation, and maintenance of the QAPP. This includes providing services such as:

- The development, maintenance, configuration control, and electronic availability of policies, procedures, and other documents (e.g., Model Reports) important to the conduct of the QAPP and Ash Fall Project;
- Concurs on the Ash Fall Project implementing procedures;
- Assignments as described in the QAPP and implementing procedures;
- The maintenance and tracking of Ash Fall Project staff qualifications;
- Providing technical support as needed to assist in the conduct of any management assessments and in the coordination of training activities;
- Approves the Corrective Action Reports that are issued for Ash Fall Project activities;
- Maintaining the database for controlling the data supporting this project;
- The maintenance and storage of the records associated with the implementation of Ash Fall Project activities.

The EMCBC Assistant Director, Office of Technical Support and Asset Management reports to the ORP Engineering Lead for Ash Fall Project activities.

1.4 EMCBC Assistant Director, Office of Information Resource Management

The EMCBC Assistant Director, Office of Information Resource Management has responsibility for:

- The coordination, procurement, maintenance, and storage and closure of the computers that will be used for executing the DRI activities, and the USGS/NOAA models;
- Maintaining the computer operating system (software and hardware), including the data for future turnover to the ORP;
- Development of any technical software procedures supporting the Ash Fall Project.

The EMCBC Assistant Director, Office of Information Resource Management reports to the ORP Engineering Lead for Ash Fall Project activities and also

communicates with the EMCBC Assistant Director, Office of Technical Support and Asset Management.

1.5 Ash Fall Project QA Lead

The Ash Fall Project QA Lead is responsible for assisting in the establishment of the QA Program for the Ash Fall Project and conducting QA oversight of the Ash Fall Project activities. The QA Lead will assist in providing QA training for participants conducting Ash Fall Project work in accordance with the QAPP and implementing procedures. The QA Lead reports to the EMCBC Assistant Director, Office of Technical Support and Asset Management.

1.6 United States Geological Survey (USGS)

The ORP has executed an interagency agreement with the USGS to use modeling to derive a probability histogram of airborne tephra concentration at the Hanford Site given an eruption at Mount St. Helens. USGS is responsible for delivering a report that includes probability histograms of airborne ash concentration and ash fall thickness at the Hanford Site during a future Mount St. Helens eruption based on large-scale Monte Carlo simulations of ash dispersal. A secondary role of the USGS is to analyze tephra collected by the DRI for ash resuspension studies.

1.6.1 A previous USGS analysis (USGS Open File Report OF2011-1064, Hoblitt and Scott, 2011) has indicated that a large volcanic eruption at Mount St. Helens could result in substantial ash fall at the site of the Hanford Waste Treatment Plant (approximately 200 km distant from the volcano), thus disrupting nuclear waste processing operations. Consequently, an important design consideration is the maximum airborne concentration that might occur at the site; in particular, what is the maximum airborne ash concentration that might exist at Hanford after a volcanic event with recurrence intervals of 2,500 and 10,000 years.

1.6.2 The USGS Ash3d program has gained global acceptance and has been the subject of many published and peer reviewed scientific papers. However, it cannot predict wind re-suspension of ash.

1.6.3 The USGS staff is responsible for the model simulations to refine estimates of thickness of deposits and airborne ash concentration at Hanford during large eruption events from Mount St. Helens. The USGS will perform the following activities:

- Support QA procedure development for EMCBC/QA Lead and execute scope of work in accordance with final QA procedures.
- Utilize an approach using computer simulations of ash transport deriving a probability histogram of airborne tephra concentration for Hanford assuming an eruption at Mount St. Helens.
- The results of the estimated computer simulations will replace the probabilities P2, P3 defined in Hoblitt & Scott (USGS Open-File Report 2011-1064), and the calculation in that report converting mass per unit area of the deposit (M) to airborne concentration (C).
- Combined with the probability P1 of Hoblitt & Scott (2011) these results will determine threshold concentrations with 2,500 or 10,000 year recurrence intervals.
- Simulations will be run using USGS Ash3d Model (Schwaiger et al., 2012) calculating tephra transport during volcanic eruptions in 3-D; time-varying wind field producing maps of deposition; plots showing deposition accumulation with time & location; and, airborne concentration with time at specified location.
- Model inputs will include vent location (Mount St. Helens); erupted volume; plume height; eruption duration; 3-D numerical wind field and size distribution of the tephra (may be modified from that of the erupted material considering aggregation or clumping of particles in the atmosphere).
- Simulations will be run using a Markov Chain Monte Carlo approach (for each model run inputs such as plume height, duration, erupted volume, and grain size distribution shall be randomly sampled from reasonable ranges of values).
- For the wind field, USGS will use NOAA's global NCEP/NCAR Re-analysis 1 dataset (Kalnay et al., 1996) covering the period of January 1, 1948 to present; USGS will choose a random start time within this timeframe; from each run, the maximum airborne concentration at ground level and thickness of ash deposits will be noted.
- From the results, USGS will determine the fraction of simulation that result in more than, for example, 50, 100, 500, 1,000 mg/m^3 concentration at ground level at the Hanford Site.
- These data will be used in a probability histogram (similar histograms shall be derived for tephra thickness and mass loading).
- Perform particle size analysis on samples being used in the DRI work scope including laser particle size distribution and sedigraph.
- USGS sediment laboratory shall perform particle characterization for DRI.
- Provide NOAA with area/thickness; particle size distribution.

- Work with the DRI on the sampling plan for inputs to particle size distribution, and review/comment on the DRI sampling plan.
- Provide a periodic status report on scope, schedule and budget.

The USGS staff reports to the ORP Engineering Lead for Ash Fall Project activities.

1.7 Desert Research Institute (DRI)

DRI is responsible for the sampling and testing related to the physical-chemical-mineralogical characterization of collected ash samples, and the development of ash resuspension relationships using the PI-SWERL®.

1.7.1 Sample & Testing Plan

DRI will complete a Sampling and Analysis Plan and will include the applicable QA requirements. The plan will identify the potential locations for collecting bulk and PI-SWERL® samples and provide a preliminary assessment of the suitability of each location. It will also detail sampling criteria and procedures to include a minimum number of samples to be collected from each landscape or surface type in order to adequately represent a range of conditions, identify the range of analytical methods that will be used on bulk and PI-SWERL® samples, and provide a draft path to completion so that it is clear how the sampling will assist in achieving project technical objectives.

1.7.2 Memorandum of Milestone Completion for Conducting Sampling and Testing

DRI will provide a memorandum ascertaining the completion of the sampling and testing activities which will include the techniques listed below that will be performed by DRI.

1.7.2.1 Collecting site-specific samples:

Sampling in the field can be divided approximately into two types of activities, PI-SWERL® measurements and collection of bulk materials for subsequent laboratory/wind tunnel analysis.

A. PI-SWERL® testing:
PI-SWERL® testing will be conducted either in-situ at the site of deposited ash, in the lab on bulk samples retrieved from field sites, or both. The DRI staff have substantial experience operating the PI-SWERL® on wind erodible sediments and

soils. It is expected that most of that expertise can be directly applied to samples of ash. However, some changes in procedure may be required to accommodate differences between ash and soil-derived dust. PI-SWERL® will be operated using standard Hybrid Step/Ramp test cycles, with the parameters of the cycles chosen to appropriately reflect the wind conditions that are being simulated.

B. Bulk samples for subsequent analysis:
Bulk samples will be collected for two possible purposes. First, relatively small amounts of bulk material may be collected to characterize particle sizes and chemical content of some specific ash deposits. This is useful for assessing comparability with Mount St. Helens ash. Second, larger (order of tenths of cubic yard) amounts of bulk material may be collected in the field for subsequent PI-SWERL® and other testing in the laboratory.

1.7.2.2 Sample analysis techniques

A. Bulk chemistry
Chemical analysis may be conducted on particles that have been collected on filter samples using a variety of techniques. These are generally established techniques in air quality work. The simplest is gravimetric weighing of filters for determining how much mass is found on them. The specific types of analyses and associated procedures will be identified in the Sampling and Analysis Plan.

B. Mineral analysis
There are two techniques that are often used together for mineral analysis of samples. They are X-ray diffraction (XRD) and scanning electron microscopy (SEM) - usually with energy dispersive X-ray spectrometry (EDS). XRD provides a bulk analysis of the minerals that are present in a sample. SEM allows the user to look at individual particles collected on a substrate (filter). This is useful for identifying minerals visually, determining the shape and angularity of mineral particles, and examining associations between multiples minerals (e.g., clustering of clays around quartz). Details for how samples will be analyzed for mineral content

and whether or not this will be performed by DRI or the USGS will be provided in the Sampling and Analysis Plan.

1.7.3 Preliminary Analysis Reporting

DRI will submit a Preliminary Analysis Report detailing the findings of the testing, sampling, and analysis. The analysis includes the threshold wind speed for ash resuspension following deposition, and the potential strength of particle resuspension rates under wind conditions expected at the Hanford Site. The report will be in a technical format with a detailed description of the methods, results, analyses, and limitations. The report will be accompanied by a presentation to the other project participants.

1.7.4 Follow-up Analysis Completion

It is anticipated that despite close coordination over the duration of the Ash Fall Project, the analyses conducted in the Preliminary Analysis Report will require some modification to provide maximal utility to the modeling partners, NOAA and USGS. This modification can include analysis with a different set of statistical tools, inclusion or exclusion of certain data based on sound scientific reasoning, recalculation of dust emission values based on varying wind parameter (e.g., one hour average versus maximum gust). The modifications and supplemental information provided will be documented as an addendum to the Preliminary Analysis Report. This addendum will be the final deliverable.

The DRI staff reports to the ORP Engineering Lead for Ash Fall Project activities.

1.8 National Oceanic and Atmospheric Administration (NOAA)

ORP has executed an interagency agreement with NOAA to perform a HYSPLIT model assessment to determine the threshold concentration of ash at the Hanford Site due to wind resuspension of distal ash deposits. NOAA will be responsible for estimating the ash concentrations arising from resuspension of volcanic ash material deposited around the Hanford Site, based on data to be provided by the USGS and DRI. An analysis period of approximately 30 years will be used to determine the probability and variability of resuspension events. The HYSPLIT model will be used as the main tool to perform the calculations.

1.8.1 This work requires empirical determination of transport properties of volcanic ash representative of distal deposits that would result from a Mount St. Helens eruption. NOAA will perform the following activities:

- Support QA procedure development for EMCBC/QA Lead and execute scope of work in accordance with the approved QAPP and QA procedures.
- Work with DRI, USGS, project peer reviewers, ORP and EMCBC supporting technical work scope.
- Collection of historical cases of airborne ash concentrations arising from re-suspension of surface deposited volcanic material. These datasets not only will include the 1980 eruption of Mount St. Helens but also as many cases as possible to diversify the characteristics of the ash sampled (particle size, composition, compaction conditions, etc.) because the ash specifications of future eruptions may not be exactly like the 1980 case.
- Empirically calibrate the flux equations based on the historical data and determine the best parameters that describe the phenomena under study using the HYSPLIT model. A numerical model will be used to generate the meteorological data for this calibration.
- Compare the empirically derived parameters with the ones derived from direct flux (PI-SWERL®) measurements (if available) and determine the appropriate values to use for a climatological re-suspension calculation.
- Use the Hanford Site meteorological network and/or other meteorological data representative of the area where the ash deposit occurred that could potentially influence the Hanford Site to determine the potential number of re-suspension days and then compare with available modeled meteorological data for each of these events. In addition, the meteorological conditions during the re-suspension days will be compared to lower resolution meteorological model analysis archives (30 years or more) to determine the probability of these events and the variability of the meteorological conditions (wind, rain, etc.). In the event insufficient meteorological data (too few re-suspension cases) are available from the Hanford Site measurements or if the lower resolution meteorological model analysis is not able to properly match the available measured values, NOAA will run the Weather Research and Forecasting model at high resolution for the entire analysis archive period (~ 30 years) to determine the probability and variability of conditions for the re-suspension events.
- Run the HYSPLIT model to estimate the air concentrations of ash for the re-suspension periods and the entire climatological period based on the parameters that best fit the case studies observations as well as those based on direct flux measurements (if available). USGS will

provide NOAA information on the ash deposit 'footprint', in other words, the location of the deposited ash that may be re-suspended, and if possible, information on the ash particle size distribution of the deposit. NOAA will produce a probability histogram for concentration of ash due to wind resuspension similar to the histogram produced by the USGS for concentration of ash due to ash fallout from an eruption. The information from this histogram may be combined with the information from the probabilistic tephra hazard maps and the estimated probability of a Mount St. Helens eruption to estimate the concentration of ash due to wind resuspension which would have a 10,000 year recurrence interval.

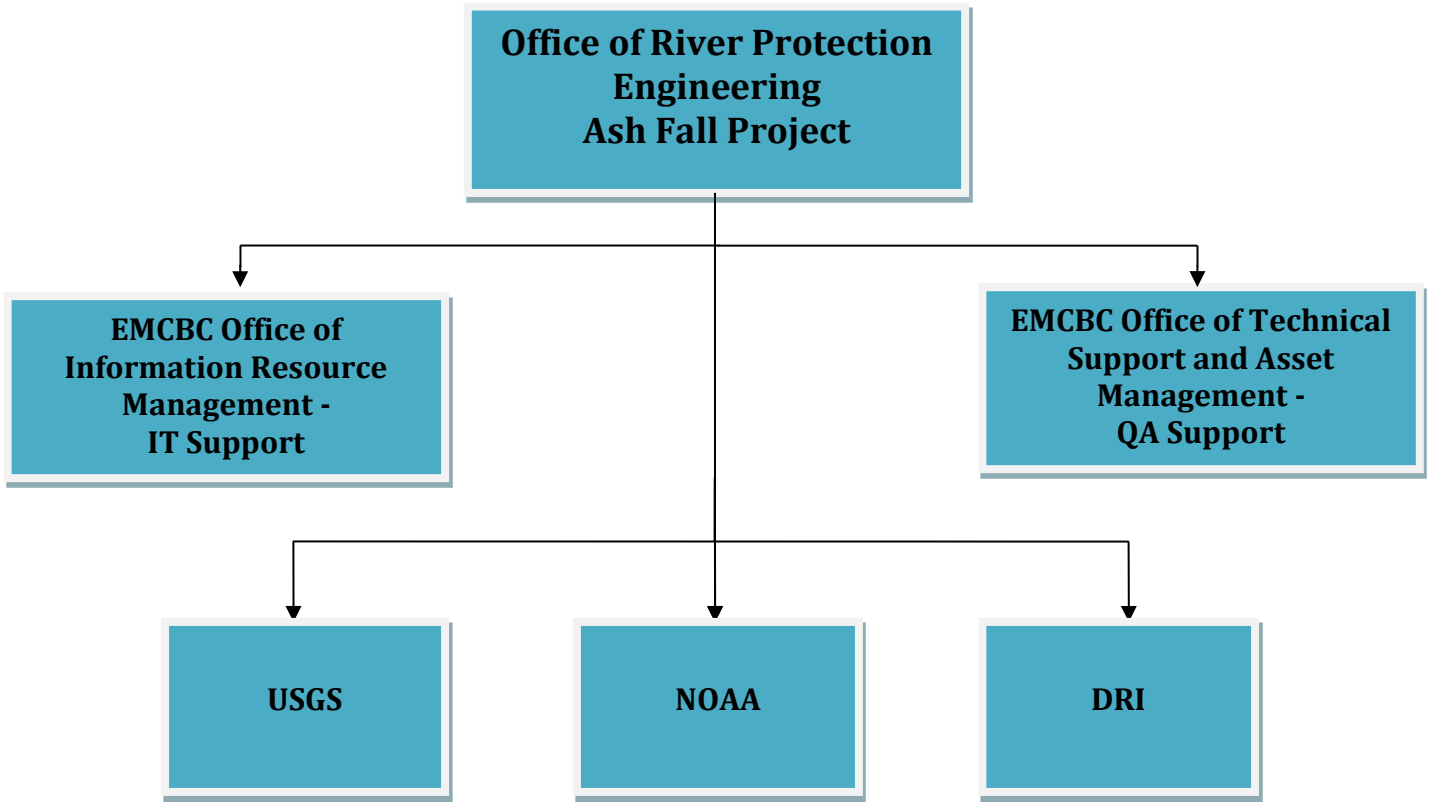
- Provide a periodic status report on scope, schedule and budget.

The NOAA staff reports to the ORP Engineering Lead for Ash Fall Project activities.

1.9 Differences of Opinion

Differences of professional opinion regarding the Ash Fall Project shall be brought to the attention of the ORP Engineering Lead and EMCBC Assistant Director, Office of Technical Support and Asset Management and, if not resolved, shall be elevated to higher levels of management consistent with DOE Order 442.2, *Differing Professional Opinions for Technical Issues Involving Environment, Safety and Health Technical Concerns*. For more guidance, refer to the DOE Environment, Health, Safety, and Security website (www.energy.gov/ehss/environment-health-safety-security).

FIGURE 1 – ORGANIZATIONAL STRUCTURE



EMCBC	Environmental Management Consolidated Business Center
USGS	United States Geological Survey
NOAA	National Oceanic and Administrative Association
DRI	Desert Research Institute
QA	Quality Assurance
IT	Information Technology

2.0 QUALITY ASSURANCE PROGRAM

The EMCBC Office of Technical Support and Asset Management shall establish, implement and maintain a QAPP to control work activities that affect the quality of the Ash Fall Project conducted in accordance with the EM-QA-001 and NQA-1, 2008/2009a. The QAPP shall provide oversight over activities to the extent consistent with their importance. The oversight program requirements shall be implemented through approved procedures developed to control the activities that affect the quality of the tasks performed under the QAPP which is developed to meet the EM-QA-001 QA program and NQA-1 2008/2009a, Subpart 3.2, *Guidance on the Control of Scientific Investigations*, and Subpart 4.2, *Guidance on Graded Application of Quality Assurance (QA) for Nuclear-Related Research and Development* which requires data accuracy when conducting research activities. The QAPP describes the activities applied to this research in a graded fashion to accomplish the task of model development/validation and ash fall collection in support of the models.

The AFP-MTX-1.0, *Ash Fall Project Implementation Requirements Matrix*, Attachment A is established, and will be updated as necessary, to demonstrate the relationship between the EM-QA-001, NQA-1-2008/2009a and the QAPP sections to the Ash Fall Project implementing documents.

QA documents developed for this program shall be reviewed and approved and concurred at a minimum by the QA Lead, ORP Engineering Lead, and Assistant Director, Office of Technical Support and Asset Management. Prior to performing activities that affect the quality of tasks conducted for the program, personnel shall be: 1) qualified to appropriate education and experience; 2) trained to the appropriate implementing documents; and 3) indoctrinated in the requirements of the QAPP.

Personnel indoctrination, training, qualification and certification shall be performed in accordance with the established procedures. The process shall ensure that indoctrination and training is completed prior to performing the work. The training shall be commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person.

The ORP Engineering Lead shall conduct a management assessment of the project as needed to provide oversight of ongoing work at a frequency commensurate with the status and importance of work. For clarification - only one management assessment will be conducted on this project due to the short life cycle of this project. The ORP Engineering Lead with assistance of the QA Lead shall direct the management assessment of the Ash Fall Project and shall be responsible for planning, performing, and evaluating the effectiveness of the QAPP. The results will be reported to the appropriate management.

3.0 DESIGN CONTROL

Design control activities are not a part of this program at this time with the exception of Data Control, Software, and the Control of the Electronic Management of Data requirements. If design activities become a responsibility of the program later, then the EMCBC Assistant Director, Office of Technical Support and Asset Management shall develop the appropriate implementing document to ensure compliance with EM-QA-001.

The procedures developed to address Data Control (Section 3.1), Software (Section 3.2) and Sample Control (Section 8.1) shall use a graded approach describing the requirements from NQA-1-2008/9a, including Subpart 2.7, *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications*, Subpart 3.2, *Guidance on the Control of Scientific Investigations*, and Subpart 4.2, *Guidance on Graded Application of Quality Assurance (QA) for Nuclear-Related Research and Development*.

The QAPP is intended to describe the guidance on controls of scientific investigations that can provide an adequate quality pedigree for the output of these Ash Fall Project models.

3.1 DATA CONTROL

The major products of the Ash Fall Project are the data development, collection of data to support the implementation of two models (Ash3d and HYSPLIT), and the collection of data by DRI (PI-SWERL®) including any analytical analysis results to support these models. These models must be validated so that the outcome can be defensible during future reviews by external organizations. Procedures shall be developed to control the data development processes and for the use of this data. Model validation procedures shall also be developed to provide for the controls for these areas.

3.2 SOFTWARE

The Ash Fall Project software used for the modeling activities (e.g., Ash3d and HYSPLIT) will be qualified based on several important factors such as the use of previous published scientific papers, their use based on the acceptance by the scientific community, and through previous peer reviews. The use of the software supporting the modeling activities will also be reviewed in accordance with the formal Ash Fall Project peer review.

Currently, the project does not anticipate the need for any acquired software to perform the necessary modeling. If there is a need in the future, the software will be purchased and controlled in accordance with the QAPP, applicable Administrative Procedures (APs) and the Software Management Plan (SMP).

> **Note:** The project may acquire software such as MATLAB and Excel, however, these are not software that require validation. Any calculations performed using these types of software will be verified in accordance with the software AP (for calculations). The project may acquire compilers and languages (e.g., Python), however, these also do not require validation. The project will check and control the utilities created with these development tools and control the development tool versions.

Any software required to be developed for use on the Ash Fall Project for design, analysis, or testing will be controlled in accordance with an approved software procedure. In addition, a SMP will be developed in accordance with the AP to support software prerequisites, conditions, processes, etc.

The following requirements address developed software which will be controlled through its software lifecycle; the period of time that begins when a software product is conceived and ends when the software is no longer available for use. The AP may use a graded approach that describes documentation requirements based on importance to safety and how the software was purchased or created. A software lifecycle typically includes a concept phase, requirements phase, design phase, implementation phase, test phase, installation and checkout phase, operation and maintenance phase, and, sometimes, a retirement phase. These phases may overlap or be performed iteratively, depending on the software development approach used.

For design analysis including modeling, documentation of computer programs used will be sufficiently detailed such that a technically qualified person can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Computer programs acceptable for design analysis will be pre-verified or the results verified with the design analysis for each application. Pre-verified computer programs will be verified to show that they produce correct solutions for the encoded mathematical model within defined limits for each parameter employed. Pre-verified encoded mathematical models will be shown to produce a valid solution to the physical problem associated with the particular application.

Software configuration management is described in the AP and includes methods for configuration identification, change control, and status control. Configuration items will be maintained under configuration management until the software is retired. A software baseline will be established at the completion of each activity of the software design process. Approved changes created subsequent to a baseline will be added to the baseline. A baseline will define the most recently approved software configuration. A labeling system for configuration items will be implemented that uniquely identifies each configuration item, identifies changes to

configuration items by revision, and provides the ability to uniquely identify each configuration of the revised software available for use.

Change control for software will be formally documented. The documentation will include a description of the change, the rationale for the change, and the identification of affected software baselines. The change will be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes will be made to software baselines. Appropriate verification activities will be performed for the change. The change will be appropriately reflected in documentation, and traceability of the change to the software design requirement will be maintained. Appropriate acceptance testing will be performed for the change.

The status of configuration items resulting from the software design will be maintained current. Configuration item changes will be controlled until they are incorporated into the approved product baseline. The controls will include a process for maintaining the status of changes that are proposed and approved, but not implemented. The controls will also provide for notification of this information to affected organizations.

Software design requirements will be identified, documented, and their selection reviewed and approved. The software requirements will identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.

The software design will be documented and will define the computational sequence necessary to meet the software requirements. The documentation will include, as applicable, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures, and the applicable relationships between data structures and process structures. This documentation may be combined with the documentation of the software design requirements or the computer program listings resulting from implementation of the software design.

Software design verification will be performed by a competent individual(s) or group(s) other than those who developed and documented the original design, but who may be from the same organization. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design, or the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews do not satisfy the intent for the QA program. The results of verification will be documented with the identification of the verifier indicated. Software verification methods will

include any one or a combination of design reviews, alternate calculations, and tests performed during computer program development. The extent of verification and the methods chosen are a function of the complexity of the software, the degree of standardization, the similarity with previously proved software, and the importance to safety.

The AP shall provide the requirements for the acquisition, development, operation, maintenance, and retirement of software. The appropriate requirements to be used will be based on a graded approach. Implementation of policies, procedures, project specific plans, specifications, or work practices, etc., will provide the framework for software engineering activities to the extent necessary to comply with customer requirements.

Ash Fall Project software engineering activities include the following elements, as appropriate: (1) software acquisition method(s) for controlling the acquisition process for software and software services; (2) software engineering method(s) used to manage the software lifecycle activities; (3) application of standards, conventions, and other work practices that support the software lifecycle; and (4) controls for support software used to develop, operate, and maintain computer programs.

The appropriate software engineering elements, described in the AP, will define the baseline documents that are to be maintained as records. The appropriate software engineering elements, described in the AP, will define control points and associated review requirements. Reviews of software will ensure compliance with the approved software design requirements. Although multiple review requirements are specified within this software section, the reviews may be performed and documented separately or combined, as appropriate. One review will consider the requirements related to the activities of preparing the computer program for acceptance testing. This review can be combined with or be part of the software design verification. Another review will provide assurance of the satisfactory completion of the software development cycle, including acceptance testing. This review can be combined with or be part of the software design verification. Individual(s) familiar with the design detail and the intended use of the computer program will be included in the review. Reviews will identify the participants and their specific review responsibilities. Documentation of review comments and their disposition will be retained until they are incorporated into the updated software. Comments not incorporated and their disposition will be retained until the software is approved for use. When review alone is not adequate to determine if requirements are met, alternate calculations will be used, or tests will be developed and integrated into the appropriate activities of the software development cycle. Tests performed in support of a review can be used to complement acceptance testing. The tests and test results will be included in the acceptance testing documentation. Such tests will be subjected to the same criteria as the acceptance

tests. These tests do not substitute for performing the comprehensive, end of development, acceptance test.

The appropriate software engineering elements, described in the AP, will identify when configuration baselines are to be established. Configuration items to be controlled will include, as appropriate, documentation (e.g., software design requirements, instructions for computer program use, test plans, and results), computer program(s) (e.g., source, object, backup files), and support software. The software configuration change control process will include initiation, evaluation, and disposition of a change request, control and approval of changes prior to implementation, and requirements for retesting (e.g., regression testing) and acceptance of the test results.

The method for documenting, evaluating, and correcting software problems is described in the applicable AP. It describes the evaluation process for determining whether a reported problem is an error or other type of problem (e.g., user mistake). It defines the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation. When the problem is determined to be an error, the method will provide, as appropriate, for how the error relates to appropriate software engineering elements, how the error impacts past and present use of the computer program, how the corrective action impacts previous development activities, and how the users are notified of the identified error; its impact; and how to avoid the error, pending implementation of corrective actions. The problem reporting and corrective action process described in an AP will address the appropriate requirements for corrective actions.

Utilization of test plans and test cases as the method of acceptance to demonstrate the capabilities within the limitations will be a method for qualification. Software operating instructions for use (e.g., user manual) within the limits of the dedicated capabilities will be required to be supplied. The resulting documentation and associated computer program(s) will establish the current baseline. Subsequent revisions of acquired software received from software suppliers will be maintained and processed in accordance with this section.

Software engineering method(s) will be documented as required by the AP. The selected software engineering method will ensure that software lifecycle activities are planned and performed in a traceable and orderly manner.

Software design requirements in the AP will specify technical and software engineering requirements. Applicable reference drawings, specifications, codes, standards, regulations, procedures, or instructions that establish software design requirement testing, inspection, and acceptance criteria will be identified. Security requirements will be specified commensurate with the risk from unauthorized

access or use. Software design requirements will be traceable throughout the software lifecycle.

An integral part of software design is the design of a computer program that is part of an overall system. Thus, the software design will consider the computer program's operating environment. Measures to mitigate the consequences of problems, as identified through analysis, will be an integral part of the design. These potential problems include external and internal abnormal conditions and events that can affect the computer program.

Software design verification will evaluate the technical adequacy of the design approach and ensure internal completeness, consistency, clarity, and correctness of the software design and will verify that software design is traceable to the software design requirements. Software design verification will include review of test results and the software. The requirements for the software design verification activity will be documented in the software engineering method as required by the AP.

The acceptance testing activity will demonstrate that the computer program adequately and correctly performs all intended functions (i.e., specified software design requirements). Acceptance testing will demonstrate, as appropriate, that the computer program properly handles abnormal conditions and events as well as credible failures, does not perform adverse unintended functions, and does not degrade the system either by itself, or in combination with other functions or configuration items. Acceptance testing will be performed prior to approval of the computer program for use.

Configuration items will be under configuration change control prior to starting acceptance testing. Acceptance testing will be planned and performed for all software design requirements. Acceptance testing ranges from a single test of all the software design requirements to a series of tests performed during computer program development. Performance of a series of tests provides assurance of correct translation between activities and the proper function of individual modules. Testing will include a comprehensive acceptance test performed in the operating environment prior to use. The test plans, test cases, and test results will be documented, reviewed, and approved prior to use of the computer program in accordance with Test Control requirements of this QAPP and APs. Observations of unexpected or unintended results will be documented and dispositioned prior to test result approval. The acceptance testing of changes to the computer program will be subjected to selective retesting to detect unintended adverse effects introduced during the change. Such testing will provide assurance that the changes have not caused unintended adverse effects in the computer program, and verify that a modified system(s) or system component(s) still meets specified software design requirements.

After the software is approved for use and installed in the operating environment, the use of the software will be controlled in accordance with approved procedures and instructions. These include, as appropriate, application documentation (e.g., application log), access control specifications, computer system vulnerability protections, problem reporting and corrective action, in-use tests, and the configuration change control process.

The appropriate software engineering elements, as described in the AP, will identify how changes to the software are controlled. Typically, changes are in response to any one of the following: enhancement requests from the user community, revisions to software based on software design requirements, changes to the operating environment and changes to computer system vulnerability protections, and reported software problems that must be corrected.

Retirement of the software and its use will be addressed in the procedures as appropriate.

Support software includes software tools and system software. As appropriate, the software engineering method, software acquisition method, or both will establish the need for software tools. Software tools will be evaluated, reviewed, tested, accepted for use, and placed under configuration control as part of the software development cycle of a new or revised software product. Software tools that do not affect the performance of the software do not need to be placed under configuration control. In cases involving modifications of software products using the software tools, the configuration of the support software associated with that modification will be managed. Changes to the software tool will be evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

System software consists of the on-line computer programs used to provide basic or general functionality and facilitate the operation and maintenance of the application computer program. Examples include lower-level software layers, assemblers, interpreters, diagnostics, and utilities. System software will be evaluated, reviewed, tested, and accepted for use as part of the software development cycle of a new or revised software product. System software will be placed under configuration change control. Changes to the system software will be evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

3.3 CONTROL OF THE ELECTRONIC MANAGEMENT OF INFORMATION

This area applies to the processes and controls for the management of information that either exists or is used in an electronic format. This includes electronically formatted information used in design input, developed as design output, or

developed as an output of scientific investigation or performance assessment modeling and analysis.

Development, acquisition, and modification of software, including database applications or software that performs functions of analysis or calculation, shall be controlled in accordance with the Section 3.2 Software requirements.

Controls shall be established to ensure that:

A. Information is suitably protected from damage and destruction during its prescribed lifetime and is readily retrievable.
B. A description is prepared of how information will be stored with respect to media, conditions, location, retention time, security, and access.
C. Storage and transfer of media are properly identified as to source, physical and logical format, and relevant date (i.e., date written).
D. The completeness and accuracy of the information input and any subsequent changes to the information are maintained.
E. The security and integrity of the information is maintained.
F. Transfers of information are error free or (where applicable) within a defined permissible error rate, to ensure that no information is lost in transfer and the input is recoverable from the output. Examples of information transfers include copying raw information from a notebook to a computerized form, copying from computer internal data storage to external data storage media (e.g., hard drive or USB memory).

4.0 PROCUREMENT DOCUMENT CONTROL

The Purchase Order (PO)/Procurement Requisitions (PR) and supporting documentation shall be prepared by the appropriate Ash Fall Project personnel who have the background and information related to the items or services to be procured. Currently, the only potential item to be procured is the DustTrak nephelometer (model 8530) for use with the DRI PI-SWERL® and the calibration service for this equipment. The PO/PR and supporting documentation shall contain the technical and quality requirements and information necessary to procure the required items or services. As appropriate to the item or service, the PR shall include the following:

- A complete description of the scope of work to be performed by the supplier.
- A description of the technical requirements including, as applicable, a reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, or item catalog number. When such documents are referenced, the revision of the document shall be indicated. All required tests, inspections, and acceptance requirements shall be specified.
- A description of the QA Program requirements to be applied by the supplier. The extent of the supplier's QA Program depends on the type and use of the item or service being obtained. The description shall include the requirement for the supplier to specify appropriate QA Program requirements to sub-tier contractors.

- Contractual language to provide access to supplier and sub-tier contractor facilities and records for a potential inspection/audit by Ash Fall Project representatives or other representatives or parties designated by Ash Fall Project staff.
- Provisions for hold points beyond which work cannot proceed without Ash Fall Project staff's authorization.
- A description of the documentation required for information, review, or approval and time of submittal of the documentation. When necessary, Ash Fall Project staff shall require the supplier to maintain specific QA records and retention and disposition times shall be specified.
- A description of the Ash Fall Project requirements for suppliers to report nonconformances dispositioned as use-as-is or repair to the Ash Fall Project staff for approval of the disposition.
- The content of procurement documents shall be maintained in a consistent manner throughout the PO/PR stages of the procurement process. A review of procurement documents and changes to procurement documents shall be performed by the technical staff and the QA Lead to ensure that the items and services are accurately and completely specified. Procurement document changes shall be managed and controlled at the same level as the original. Changes to procurement documents, as the result of the evaluation of the supplier's response, shall be reviewed to ensure that procurement document content is consistent and correct; and that any exceptions/changes requested or specified by the supplier are consistent with the quality of the item or service.
- As appropriate to the procurement, QA clauses or QA requirements shall be invoked to require such actions as pre-award evaluation of the supplier, independent receiving inspection, source inspection or source surveillance.

The Ash Fall Project does not perform commercial grade dedication (CGD) activities at this time, therefore a procedure does not need to be developed to address this area.

5.0 PROCEDURES, INSTRUCTIONS, AND DRAWINGS

The established procedures shall include appropriate guidance to control the performance of work including, but not limited to, a description of the activity to be performed; the responsibilities and interfaces affected by the document; technical and quality requirements; qualitative or quantitative acceptance criteria; prerequisites, limits, precautions, environmental conditions as applicable; and required QA records. The ORP Engineering Lead and EMCBC Office of Technical Support and Asset Management shall structure implementing procedures so that quality is achieved and maintained by those who have been assigned responsibility for the work performance.

6.0 DOCUMENT CONTROL

The Ash Fall Project staff shall perform its work in accordance with controlled implementing documents. If personnel cannot accomplish the work as described in its implementing documents or the accomplishment of such work would result in an undesirable condition, personnel shall suspend work in accordance with an approved procedure. The work shall not resume until the changes to the implementing documents are formally changed in accordance with established processes to reflect the correct work practices.

Implementing documents shall establish measures to assure documents, including changes, are reviewed for adequacy, approved for release, and distributed to and used at the location where work is being performed. Individuals, other than the preparer of the document, who are technically competent and qualified, shall review project documents, including changes, for applicability, correctness, completeness, and accuracy.

The ORP Engineering Lead and EMCBC Assistant Director, Office of Technical Support and Asset Management are responsible for approving the document(s) for release. Documents that are used to perform work shall be made available and used at the work location. Documents shall be identified with effective dates. Only approved current implementing documents shall be made available in accordance with established procedures. Obsolete or superseded documents shall be managed in such a way to ensure that they are not available to be used.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND COMPONENTS

Ash Fall Project staff shall use a systematic approach in the quality related procurement planning process. The planning shall result in the documented identification of the procurement methods and the responsibilities of Ash Fall Project staff involved. Currently, the only potential item to be procured is the DustTrak nephelometer (model 8530) for use with the DRI PI-SWERL® and the calibration service for this equipment.

Planning shall begin as early as practical and identify the procurement methods to be used and the sequence of actions and milestones to be achieved. The planning process, as applicable, shall address the following:

- procurement document preparation, review, and change control
- selection of suppliers
- control of supplier performance
- verification activities such as surveillances, inspections, and/or audits required
- control of nonconformances
- corrective action controls
- item or service acceptance
- QA records.

Measures shall be established to ensure that suppliers are selected based on an evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents prior to award of contract. These measures shall include provisions for evaluation, selection, and documentation of results. Source evaluation shall include one or more of the following:

- evaluation of the supplier's history, which reflects current capability to provide an identical or similar product that performs satisfactorily in actual use
- a review of the supplier's current QA records supported by documented qualitative and quantitative information that can be evaluated objectively
- supplier's technical and quality capability as determined by a direct evaluation of the facilities and personnel and the implementation of their QA Program.

Bid evaluation, as applicable, shall be performed to ensure the supplier's response addresses all aspects of the procurement document and to obtain commitments to resolve unacceptable quality conditions prior to award of contract. This evaluation shall be performed by designated Ash Fall Project staff to ensure that technical, quality, and supplier capability requirements are met and that all exceptions or alternatives in the supplier's proposal are evaluated.

Ash Fall Project staff shall establish measures to verify supplier performance as deemed necessary. These measures, as applicable to the procurement, shall address the following:

- establishing an understanding of Ash Fall Project specifications and the provisions of the procurement documents with the supplier
- requiring the supplier to identify planning techniques and processes used to fulfill procurement requirements
- reviewing supplier documents detailing activities associated with the fabrication of an item or the performance of a service
- establishing a method to process change information
- establishing the method for the exchange of documents between Ash Fall Project staff and the supplier.

Provisions shall be made in procurement documents to permit Ash Fall Project staff to perform verifications of the supplier's performance when deemed necessary. Activities to verify supplier conformance to requirements shall be recorded.

Measures for the control, handling, and approval of supplier-generated documents shall be established. These measures shall ensure that the submittal of suppliers' documentation is accomplished in accordance with the procurement document and provides for the evaluation of technical, inspection, and test data against acceptance criteria.

Ash Fall Project staff and the supplier shall ensure that measures are established and documented to control changes in procurement documents.

Ash Fall Project staff shall establish the methods by which an item or service is to be accepted. The methods employed shall be based on one or more of the following: source verification, receiving inspection, or a supplier Certificate of Conformance. Source verification shall be performed based on the relative importance, complexity, and quantity of the item or service. Source verification shall be performed by qualified personnel assigned to check, inspect, audit, or witness activity performed by the supplier. Verifications are performed primarily to preclude delivery of items or services that have hidden defects or other characteristics difficult to verify after delivery. Source verification activities for item acceptance shall consist of plans to perform or witness inspections, tests, and examinations of items at predetermined points.

> **Note:** The use of Third-Party audits are acceptable and shall be reviewed by the Ash Fall Project QA Lead. The AP for Supplier Control will provide the level of rigor for the use and acceptance of a third-party audit.

The requirements for a supplier Certificate of Conformance shall be established and address:

- the identity of the purchased item or equipment
- the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications
- the procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment
- procurement requirements that have not been met, together with an explanation and the means of resolving the nonconformances
- the certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the Purchaser’s or Supplier’s QA Program
- if a Certificate of Conformance is used, Ash Fall Project staff shall require that the supplier maintain a proceduralized process that is incorporated into the supplier's QA Program
- Ash Fall Project staff shall establish the means to verify the validity of supplier Certificates of Conformance by conducting audits, independent inspections, and tests of items at a frequency commensurate with the supplier's past quality performance.

Measures shall be provided for the implementation and control of receiving inspections. These measures shall include provisions for receiving inspection activities, as necessary, to verify conformance to specified requirements, taking into account source verifications, audits, and the demonstrated quality performance of the supplier. The receiving inspection shall be performed to verify conformance of the item and documentation to procurement requirements such as configuration, identification, dimensional, physical, and other characteristics, freedom from shipping damage, and cleanliness. Receiving inspection shall

be coordinated with the review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

In cases involving procurement of services only, such as third party inspection; engineering; consulting services; auditing; and installation, repair, overhaul or maintenance work, the Purchaser shall accept the service by any or all of the following methods:

- technical verification of data produced
- surveillance and/or audit of the activity
- review of objective evidence for conformance to the procurement document requirements.

Methods for control and disposition of supplier nonconformances for items and services that do not meet procurement documentation requirements shall include:

- evaluation of nonconforming items
- submittal of nonconformance notice to Purchaser by Supplier as directed by the Purchaser.
- the submittals shall include supplier recommended disposition for use-as-is and repair along with technical justification
- nonconformances to Ash Fall Project procurement requirements or approved documents shall be submitted to Ash Fall Project staff for approval of the recommended disposition when the following occurs:
  - technical or material requirements are violated
  - requirements in supplier documents, which have been approved by Ash Fall Project staff, are violated
  - nonconformance cannot be corrected by continuation of the original manufacturing process or by rework
  - the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.
- purchaser disposition of supplier recommendation
- verification of the implementation of the disposition
- maintenance of records of supplier-submitted nonconformances.

Records shall be established and maintained to indicate the performance of the functions:

- supplier evaluation and selection
- acceptance of items or services
- supplier nonconformances to procurement document requirements, including their evaluation and disposition.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

Physical samples collected for Ash Fall Project data shall be controlled in accordance with Section 8.1 including any handling, storage, and shipping requirements.

8.1 SAMPLE CONTROL

This area of Sample Control is designed to control collected physical samples. DRI will implement this area for the collection and control of Ash samples.

General Requirements:

A. Samples shall be controlled and identified in a manner consistent with their intended use.
B. Controls shall identify responsibilities, including interfaces between organizations, for documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final use.
C. Controls shall include specifics on the location that was sampled, as appropriate.

Traceability:

A. Sample identification methods shall ensure that traceability is established and maintained from the samples to applicable implementing documents or other specifying documents.
B. Sample traceability shall ensure that the sample can be traced at all times from its collection through final use and any post-test retention that may be appropriate.

Identification:

A. A unique identifier shall be maintained on the samples or in a manner that ensures that identification is established and maintained.
B. Samples shall maintain their same unique identifier from their initial collection through final use.
C. Sample identification shall be documented and verified before the sample is released for use or analysis.
D. Sample identification methods shall include use of physical markings.
E. If physical markings are either impractical or insufficient, other appropriate means shall be employed (e.g., physical separation, labels or tags attached to containers, or other procedural control).
F. Physical markings, when used, shall:
    1. Be applied using materials and methods that provide a clear and legible identification.
    2. Not detrimentally affect the sample content or form.
    3. Be transferred to each identified sample part when the sample is subdivided.
    4. Not be obliterated or hidden by surface treatments or sample preparations unless other means of identification are substituted.

Conditional Requirements:
The controls for samples shall address the following requirements, as applicable:

A. If documents contain specific identification or traceability requirements (e.g., identification or traceability of the sample to applicable study plan, site characterization activity, or other records), those specified controls shall be implemented.
B. If samples have limited use or storage life, then methods shall be established that preclude using the sample beyond its intended use or storage life.
C. If sample storage is required, then methods shall be established for the control of sample identification that is commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:
    1. Maintenance or replacement of markings and identification tags damaged during handling or aging.
    2. Protection of identification markings subject to excessive deterioration resulting from environmental exposure.
    3. Updating related documentation.

Archiving Samples:
Implementing documents shall specify the representative samples to be archived if the need to archive samples is identified.

Nonconforming Samples:
Any physical samples that are considered nonconforming shall be discarded and not used for data collection. If any data were obtained utilizing nonconforming samples, the data are considered to be suspect and will be addressed in accordance with Section 16.0, Corrective Action of the QAPP.

9.0 CONTROL OF SPECIAL PROCESSES

Special Processes activities are not a part of this program at this time. If special processes activities become a responsibility of the program later, then the EMCBC Assistant Director, Office of Technical Support and Asset Management shall develop the appropriate implementing document to ensure compliance with the EM-QA-001.

10.0 INSPECTION

Inspection activities are not a part of this program at this time. If inspection activities become a responsibility of the program later, then the EMCBC Assistant Director, Office of Technical Support and Asset Management shall develop the appropriate implementing document to ensure compliance with the EM-QA-001. (Receipt Inspection will be conducted in accordance with Section 7.0.)

11.0 TEST CONTROL

Test Control is limited to the testing of Ash Fall Project models, Ash3d and HYSPLIT, including their associated software. Testing required to collect data to verify conformance of a computer program to specified requirements or to determine satisfactory performance for service shall be planned and executed.

Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria evaluated.

Test objectives, test requirements, and acceptance or evaluation criteria shall be provided or approved by the Ash Fall Project staff. Testing activities shall be controlled and shall have a basis described in design or other technical documents in which acceptance or evaluation criteria is described, as applicable. The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance and evaluated through Independent Reviews (IRs) or peer reviews to ensure the test requirements have been satisfied.

Test requirements and acceptance criteria for computer programs shall be documented in a Test Plan and shall include the following as applicable:

- software design verification testing shall demonstrate the capability of the computer program(s) to provide valid results for test problems encompassing the range of documented permitted usage
- computer program acceptance testing shall consist of the process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment
- in-use computer programs testing shall demonstrate required performance over the range of operation of the controlled function or process.

Testing prerequisites include calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition.

In lieu of test procedures and/or test instructions, references to appropriate sections of related documents, such as American Society for Testing and Materials (ASTM) methods, supplier manuals, approved drawings, or travelers with acceptance criteria can be used. Such documents must be adequate to ensure the quality of the work and approved in writing by the ORP Engineering Lead and the QA Lead.

For additional testing requirements implementing computer software program requirements per NQA-1 Section 400, refer to this QAPP, Section 3.2, Software.

Test procedures, plans, and/or instructions shall include:

- required tests and test sequence
- required range of input parameters
- identification of the stages at which the testing is required
- criteria for establishing test cases
- requirements for testing logic branches
- requirements for hardware integration
- anticipated output values
- acceptance criteria
- reports, records, standard formatting, and conventions.

Test results shall be documented and maintained. Test results shall be evaluated by a responsible authority to ensure the test requirements have been satisfied.

Test records shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements.

Testing records shall identify and describe, as a minimum:

- item tested
- date of the test
- tester or data recorder
- type of observation
- results and acceptability
- actions associated with any deviations noted
- person evaluating the test results.

Testing records shall identify and describe, as a minimum, for computer program testing:

- computer program(s) tested including system software used
- computer hardware used
- test equipment and calibrations, where applicable
- date of the test
- tester or data recorder
- simulation models used, where applicable
- test problems
- results and applicability
- actions taken in connection with any deviations noted
- person evaluating test results
- acceptability.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

DRI has the only equipment (PI-SWERL®) that requires calibration and control in support of the Ash Fall Project. The following requirements are intended to provide the requirements for this M&TE and will be applied in a graded approach.

The Ash Fall Project staff shall select the appropriate M&TE to ensure that the equipment is of the proper type and has the necessary accuracy and tolerance.

Measures shall ensure that tools, gages, instruments, and other M&TE used for activities affecting quality are controlled, calibrated at specified periods, adjusted, and maintained to required accuracy limits.

Selection of M&TE shall be based on the proper type, range, accuracy, and tolerance, needed to accomplish the required measurements for determining conformance to specified requirements.

M&TE shall be calibrated at prescribed times or intervals and whenever the accuracy of the M&TE is suspect. The calibration shall be performed against and traceable to certified equipment or reference standards having known, valid relationships to nationally recognized standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards. If no nationally recognized standards exist, the basis for calibration shall be documented.

Reference standards shall have a minimum accuracy four times greater than that of the M&TE being calibrated to ensure that the reference standards contribute no more than one-fourth of the allowable calibration tolerance. Where this 4:1 ratio cannot be maintained, the basis for selection of the standard in question shall be technically justified.

Calibration procedures shall identify or reference required accuracy and shall define methods and frequency of checking accuracy. The calibration method and interval for each item shall be defined based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting performance.

When M&TE is found overdue or found to be out of calibration, it shall be tagged and/or segregated, or removed from service, and not used until it has been recalibrated. If any M&TE is consistently found to be out of calibration, it shall be repaired or replaced. M&TE shall be traceable to its application and use.

When M&TE is lost, damaged, or found out of calibration, the validity of previous measurement, inspection, or test results and the acceptability of items previously inspected or tested shall be evaluated. This evaluation shall be from at least the last acceptable calibration of the M&TE. The evaluation and resulting actions shall be commensurate with the significance of the condition.

M&TE shall be properly handled and stored to maintain accuracy.

M&TE shall be used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained. M&TE and reference standards submitted for calibration shall be checked and the results recorded before any required adjustments or repairs are made.

M&TE shall be suitably marked, tagged, labeled or otherwise identified to indicate calibration status and establish traceability to calibration records.

Calibration and control measures may not be required for burettes, pipettes, mercury thermometers, rulers, tape measures, levels, and other devices, if normal commercial equipment provides adequate accuracy.

Calibration records shall be established and maintained to indicate calibration status and the capability of M&TE to satisfactorily perform its intended function. Calibration reports and certificates reporting the results of calibration shall include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements.

13.0 HANDLING, STORAGE, AND SHIPPING

Any handling, storage, and shipping activities will be controlled in accordance with Section 8.1 of this QAPP for Ash Fall Project items such as physical samples.

14.0 INSPECTION, TEST AND OPERATING STATUS

Test and Operating Status activities are not a part of this program at this time. If inspection, test and operating status activities become a responsibility of the program later, then the EMCBC Assistant Director, Office of Technical Support and Asset Management shall develop the appropriate implementing document to ensure compliance with the EM-QA-001.

15.0 NONCONFORMING MATERIAL, PARTS, OR COMPONENTS

Nonconformance activities are not a part of this program at this time. If nonconformance activities become a responsibility of the program later, then the Director of the Office of Standards and Quality Assurance shall develop the appropriate implementing document to ensure compliance with the EM-QA-001.

Note – Any physical samples that are found to be nonconforming are addressed in Section 8.1 of the QAPP.

16.0 CORRECTIVE ACTION

When conditions adverse to quality are identified, Ash Fall Project staff shall take the necessary actions to correct the condition and verify implementation of corrective action as soon as is practical.

In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified.

The Ash Fall Project corrective action system shall be documented in a manner that permits the review, evaluation, and verification of corrective action activities. The responsibilities of the participants in the corrective action process shall be described.

Where conditions adverse to quality have been identified, the extent of any impacts to other items or services shall be evaluated and appropriate action taken.

Corrective action activities shall be reviewed to determine the existence of trends. Trends, when identified, shall be evaluated as to their significance and appropriate actions taken.

A method to classify conditions adverse to quality relative to their significance shall be established that considers the impact on public safety and health, the reliability of items, regulatory commitments, and the extent to which the condition may adversely impact other items or activities. Other factors shall be included in the classification of conditions adverse to quality, including the relationship to similar, but different, conditions.

For conditions adverse to quality deemed significant, the root cause shall be determined and documented, the impact of the condition determined, and related items and activities evaluated. The methods used to determine the root cause shall determine the main underlying source of the condition which, when corrected, eliminates recurrence of the condition. If root cause analysis is required, then trained and qualified third party services may be procured.

Ash Fall Project staff shall identify the actions necessary to correct conditions adverse to quality and implement the actions. Such actions address the root cause in the case of conditions identified as significant. The implementation of corrective actions should be verified and for significant conditions, the actions will be assessed as to their effectiveness.

Corrective actions will be tracked and only considered complete when the corrective actions have been verified as completed. When delays occur in the implementation of corrective actions or corrective actions cannot be verified due to delay, notification shall be made to the management of the affected Ash Fall Project organizations.

When corrective actions have not been effective as determined by follow-up activities such as internal audits, surveillances, or reviews, further analysis shall be performed and the problem shall receive escalated management attention.

17.0 QUALITY ASSURANCE RECORDS

The Ash Fall Project shall have implementing documents that describe the process for the management of QA records resulting from the performance of Ash Fall Project activities. Implementing documents shall identify the QA records generated resulting from activities associated with the Ash Fall Project. Records shall be legible, accurate and complete, appropriate for the work, and identifiable to the item or activity to which they apply. Records may be originals or copies and shall be protected from damage, deterioration or loss until they are submitted to the EMCBC. The EMCBC shall retain the QA records until they are needed for the final disposition of the Ash Fall Project.

QA records shall furnish documentary evidence that items or activities meet specified quality requirements. QA records shall be identified, generated, authenticated, and maintained and their final disposition specified.

Records shall be considered valid records when stamped, initialed, or signed and dated by authorized Ash Fall Project personnel or otherwise authenticated. Methods for record changes shall be documented. Corrections to documents shall be reviewed and approved by the responsible individual from the originating or authorized organization.

Electronic documents shall be authenticated with comparable information as appropriate (1) with identification on the media; or (2) with authentication information contained within or linked to the document itself.

The records generated by Ash Fall Project shall be indexed and include retention times and the location of the record within the records system.

The Ash Fall Project QA records generated shall be designated as permanent (i.e., lifetime) or nonpermanent in accordance with established procedures.

The EMCBC organization responsible for receiving records shall provide protection from damage or loss. The Ash Fall Project shall implement a system for the receipt control of records for permanent storage. Such a system shall provide for designating, identifying, receiving, inspecting, and submitting the required records to storage and be so structured that the status of records can be ascertained during the receiving process.

EMCBC shall designate the location(s) for the storage of records (single or dual) and a record storage procedure shall be prepared that defines the responsibilities and means of enforcing the requirements of the procedure. The procedure shall describe the storage

facility, the filing system, the receiving of records, the accountability for records removed from storage, and a description of how supplemental information and disposal of superseded records shall be addressed.

Provisions shall be made by Ash Fall Project staff to ensure that records are maintained in a manner that minimizes the risk of loss, damage or destruction from (1) natural disasters such as winds, floods, or fires, (2) environmental conditions such as high and low temperatures and humidity, (3) infestation of insects, mold, or rodents (4) dust or airborne particles. Activities detrimental to the records shall be prohibited in the storage area. Storage facilities shall provide for the processing, storage, and retrieval of records and a list of designated individuals who have authorized access to the records shall be maintained. The Ash Fall Project has decided to maintain records in accordance with the dual storage requirements. Single storage does not apply at this time. If the Ash Fall Project decides to maintain records in accordance with single storage requirements, this QAPP will be revised to reflect this change.

Provisions shall be established to prevent damage from harmful conditions (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage.

Dual storage facilities, containers, or a combination thereof shall be at locations sufficiently remote from each other to eliminate the chance exposure to a simultaneous hazard.

Record retention periods shall be documented and maintained for their specified retention period. Records shall be bound or placed in folders, and envelopes for storage in steel cabinets or shelving. Provisions shall be made for special records (such as radiographs, magnetic media) to prevent degradation or damage during their retention period.

Provisions shall be made to ensure that the records remain retrievable after hardware, software, or technology changes.

Provisions shall be established to ensure the following when records are duplicated or transferred to the same media or to a different media for the purposes of maintenance or storage:

- duplication or transfer is appropriately authorized, and
- record content, legibility, and retrievability are maintained.

18.0 AUDITS

Audit activities are not a part of this Ash Fall Project at this time. If audit activities become a responsibility of the program later, then the EMCBC Assistant Director, Office of Technical Support and Asset Management shall develop the appropriate implementing document to ensure compliance with the EM-QA-001.

Attachment A
AFP-MTX-1.0
Ash Fall Project Implementation Requirements Matrix

EM-QA-001, Revision 1, *EM Quality Assurance Program* and NQA-1, 2008/2009a, *Quality Assurance Requirements for Nuclear Facility Applications* to Ash Fall Project Procedures Matrix

EM-QA-001, Rev. 1	**NQA-1, 2008/9a**	**AFP Procedures**
1.0 Program	1.0 Organization	AFP-QAPP-001
2.0 Personnel Qualification/Training	2.0 QA Program	AFP-QAPP-01 AFP-AP-01 AFP-AP-02
3.0 Quality Improvement	15.0 Control of Nonconforming Items 16.0 Corrective Action	AFP-AP-18 AFP-AP-19
4.0 Documents and Record	5.0 Instructions, Procedures/Drawings 6.0 Document Control 17.0 QA Records	AFP-AP-12 AFP-AP-13 AFP-AP-14 AFP-AP-20
5.0 Work Processes	5.0 Instructions, Procedures/Drawings 6.0 Document Control 8.0 Identification and Control of Items 9.0 Special Processes 12.0 Control of M&TE 13.0 Handling, Storage, and Shipping 14.0 Inspection, Test/Operating Status Software - Part II, Subpart 2.7	AFP-AP-12 AFP-AP-21 AFP-AP-13 AFP-AP-14 AFP-AP-06 N/A AFP-AP-17 AFP-AP-18 N/A AFP-AP-03 AFP-AP-04 AFP-AP-05 AFP-AP-06 AFP-AP-07 AFP-AP-09 AFP-AP-10 AFP-DI-01
6.0 Design	3.0 Design Control	N/A
7.0 Procurement	4.0 Procurement Document Control 7.0 Control of Purchased Items/Services	AFP-AP-11 AFP-AP-15 AFP-AP-16

8.0 Inspection/Acceptance Testing	8.0 Identification and Control of Items	AFP-AP-06
	Software - Part II, Subpart 2.7	AFP-AP-03
		AFP-AP-04
		AFP-AP-05
		AFP-AP-06
		AFP-AP-07
		AFP-AP-09
		AFP-AP-10
		AFP-DI-01
	10.0 Inspection	N/A
	11.0 Test Control	AFP-AP-07
	12.0 Control of M&TE	AFP-AP-17
	14.0 Inspection, Test/Operating Status	N/A
9.0 Management Assessment	2.0 QA Program	AFP-QAPP-001
		AFP-AP-01
		AFP-AP-02
	16.0 Corrective Action	AFP-AP-19
	18.0 Audits	N/A
10.0 Independent Assessment	18.0 Audits	N/A

Form 12-1 – Record of Revision

DOCUMENT: AFP-QAPP-001, *Quality Assurance Project Plan*

Revision Number	Description of Changes	Revision on Pages	Effective Date
0	Initial Issue	All	03/25/2016